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| COHEN, PONTANI, LIEBERMAN & PAVANE LLP | | | EXAMINER | |
| 551 FIFTH AVENUE | | | OSINSKI, BRADLEY JAMES | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/768,760 | Applicant(s) MINH MINER ET AL. |
| | Examiner BRADLEY J. OSINSKI | Art Unit 3767 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 October 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-55 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 6, 7, 9, 13, 16-18, 21, 23-26, 28, 31-34, 36, 39-41, 49 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Bormann et al (6,336,916).

a. Regarding claim 1, Bormann discloses an IV-solution delivery system comprising a coupling assembly having an input 210 and output 300 for coupling to the container 200 to provide flow of the solution through the coupling assembly to the output 220. A drip chamber 100 (figure 6) is shown in detail in figure 1. The drip chamber 100 has a top wall, bottom wall and a side wall 16/18, an input 1 and output 2. Input 1 couples to the coupling assembly (see figure 6) to receive solution drops formed from the flow of the solution to form a reservoir in the drip chamber. The side wall 16/18 has an opening located between the top and bottom walls, with a vent plug 10 covering the opening. The vent plug allowing air contained in the drip chamber which becomes displaced upon formation of the reservoir to be escape from the drip chamber through the vent plug. A patient conduit 230 is coupled to the drip chamber outlet (figure 6). The conduit 230 has a flow restriction device 400' capable of restricting the flow of air and liquid in the patient conduit (on/off) to allow the reservoir to achieve a level at least equal to

the height of the vent plug while air (and liquid) in the patient conduit is expelled from the termination end. Wetting of the vent plug 10 prevents the entry of air through the vent plug to the drip chamber and prevents the exit of solution from the drip chamber through the vent plug (Col.2 lines 61-64).

b. Regarding claim 6, flexible conduit 220 couples the coupling assembly output to the drip chamber and has a length such that the two may be separated so the drip chamber is capable of being positioned in close proximity to a patient and provide minimal disturbance of the coupling assembly.

c. Regarding claim 7, drip orifice 23 is located in the drip chamber top wall for forming solution drops.

d. Regarding claim 9, vent plug 10 comprises an absorbing material and a housing 10a/10b connected to the side wall opening and defining a cavity for receiving a formation of the absorbent material, where the absorbing material is a super-absorbent polymer that expands in response to wetting by the reservoir (Col. 3 lines 17-22).

e. Regarding claim 13, the surrounding cylinder of port 4 is a cannula with a cavity 4, with the absorbing material within. The cannula is secured to the sidewall opening has a first end in communication with the drip chamber and a second end in communication with the surrounding atmosphere.

f. Regarding claim 16, Bormann discloses a conduit 210 for connecting to supply container 200. Bormann further discloses a "spike" for connecting the conduit to the container (Col.5 lines 47-50)

- g. Regarding claim 17, Bormann discloses an additional venting means 101 for venting gas (Col.5 lines 55-60), the conduit is closable via control device 400.
- h. Regarding claim 18, the conduit connected to coupling 1 will assume a funnel shape as it frictionally engages the coupling and will direct solution from the container to the drip chamber.
- i. Regarding claim 21, the drip forming portion 22 may be considered part of the coupling member to form the solution into drops.
- j. Regarding claim 23, see figure 2 which shows a shield 24 connected to the side wall above the vent plug and extending across the vent plug.
- k. Regarding claim 24, see claim 1 above. The opening is formed in the side wall between the top and bottom walls and a vent plug covers the opening, the vent plug comprised of a material allowing air to escape and restricting the flow of air once wetted. (Col.3 lines 15-22).
- l. Regarding claims 25 and 26, see claim 9 above.
- m. Regarding claim 28, see claim 13 above.
- n. Regarding claim 31, see claim 1 above regarding the drip chamber.
- o. Regarding claims 32, 34 and 36, see claim 9 above.
- p. Regarding claim 33, see figures 1 and 2, which show the vent plug is a ring/band of material comprising an absorbing material and disposed over the opening in the side wall.
- q. Regarding claim 39, see claim 23 above.

- r. Regarding claim 40, see claim 1 above. The first material is disclosed as being impervious (Col.7 lines 45-47). The second material is the absorbing material addressed above.
- s. Regarding claim 41, see claim 9 above.
- t. Regarding claim 49, see claim 1 above, also see Col.10 lines 1-13. Bormann does not specifically disclose the container being at a height above the patient. However, this must occur because the principles upon which drip chambers and IV bags depend on the difference in height between the patient and IV bag to generate a pressure gradient. (hydrostatic pressure).
- u. Regarding claim 51, see clamps 400/400'.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 2. Claims 2-5, 43-48, 50, and 52-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann et al (6,336,916) as applied to claims 1 and 49 above, and further in view of Knighton (4,571,244).
 - v. Regarding claims 2 and 3, Bormann discloses additional filters (such as 101) for eliminating gas. While Bormann substantially discloses the apparatus as claimed, it does not disclose a termination end cap with a vent for allowing gas

present in the patient conduit to be eliminated through the end cap while preventing leakage of the solution. However, Knighton is drawn to a system for removing gas bubble from liquids. Knighton specifically states, "*The system is inexpensive and simple to use. A nurse or doctor merely inserts the device into the IV line. Entrapped gas flows out of the chamber through the second gas-passing filter, the gas-free fluid flows through the first fluid-passing filter into the patient.*" (Col.1 lines 66-68 to Col.2 lines 1-2) Therefore it would have been obvious to one of ordinary skill in the art to add the gas expelling device of Knighton to the end of the patient conduit of Bormann in order to further expel gas in order to avoid a gas embolism in the patient.

w. Regarding claim 4, the end plug of Knighton utilizes a hydrophilic porous material (Col.2 line 46)

x. Regarding claim 5, The flow restriction device 400' is disclosed as possibly being a clamp. (Col.5 line 45) which selectively closes the patient conduit to isolate the patent from the drip chamber.

y. Regarding claim 43, see claims 1 and 2 above.

z. Regarding claim 44, the device of Knighton is releasably attachable to the termination end (Col.1 lines 66-67).

aa. Regarding claim 45, a luer connection is notoriously well known within the art as a way of reversibly sealing medical devices together.

bb. Regarding claim 46, the end vent plug also has a hydrophobic material (Col.2 lines 48-49).

- cc. Regarding claim 47, Bormann discloses the regulating means as drip chamber 100.
 - dd. Regarding claim 48, Bormann discloses the regulating means is also a pump in that it uses gravity to generate a pressure gradient to pump fluid into a patient.
 - ee. Regarding claim 50, see claim 2 above and citation in claim 44.
 - ff. Regarding claim 52, see claim 1 above.
 - gg. Regarding claim 53, see claim 1 above.
 - hh. Regarding claim 54, the termination end cap is capable of allowing air to escape from the line and formation of the reservoir.
 - ii. Regarding claim 55, see claim 1 above. The hydrophilic filter discussed above will seal upon wetting to prevent air from further exiting through that route.
3. Claims 8, 10, 15, 19, 20, 30, 35, 38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann et al (6,336,916) as applied to claims 1, 9, 18, 26, 32 and 40 above.
- jj. Regarding claims 8, 35 and 42, while Bormann substantially discloses the apparatus as claimed, it does not disclose the opening coinciding with 1/3 of the total volume of the drip chamber. However, Bormann does disclose the side vents allowing the level to be filled to a predetermined level less than the total capacity of the housing. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to place the sidewall aperture of Bormann at a location such that the reservoir occupies

1/3 of the volume of the drip chamber because Applicant has not disclosed that utilizing only 1/3 of the volume of the drip chamber provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well as the drip chamber disclosed by Bormann. Therefore, it would have been an obvious matter of design choice to modify Ford to obtain the invention as specified in claim 8.

- kk. Regarding claims 10, see claim 12 above.
- ll. Regarding claims 15 and 30, Bormann discloses meshes or screens to support the absorbent material (Col.7 lines 36-39). Bormann does not disclose expressly a trapezoidal housing cavity. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to give the housing cavity a trapezoidal cross-section because Applicant has not disclosed that a trapezoidal shaped cavity provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Bormann because both shapes of the cavities will retain the vent plug. Therefore, it would have been an obvious matter of design choice to modify Bormann to obtain the invention as specified in claim 15.
- mm. Regarding claims 19 and 20, While Bormann substantially discloses the apparatus as claimed including an air filter 101 above the interfacing area to allow trapped air in the coupling member to escape , it does not disclose a

membrane in the funnel portion to prevent air from entering the drip chamber.

However, It would have been obvious to one of ordinary skill in the art at the time the invention was made to move the filter (which includes a hydrophilic absorbent membrane of Bormann) to the end of the coupling assembly line (interfacing area) since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 and forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893)

4. Claims 11, 12, 14, 27, 29 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann et al (6,336,916) as applied to claims 1, 24, 25 and 32 above, and further in view of Bucevschi et al (6,833,488).

nn. Regarding claim 11, Bormann discloses housings 10b in communication with the drip chamber and a second end 10a in communication with the atmosphere. The cavity receiving the absorbing material 10 (see claim 9). Bormann further discloses the device may have additional components including vents (Col.5 line 58). Also disclosed is a liquophobic portion as part of porous medium 10, which will not absorb/expand with water and acts as a filter at the first end (Col.6 lines 35-36). 10b passes gas as well and acts a venting membrane (Col.6 lines 36-37). While Bormann substantially discloses the apparatus as claimed, it does not disclose the polymer material in granular form. However, Bucevschi discloses absorbing materials are polymer based and can be presented in a variety of forms, including powder, granule, microparticle, film

or fiber. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the absorbing structure of Bormann of a granules as taught by Bucevshi because it is a known form for absorbent polymers and there would be only the expectation of success of providing a different form for the absorbent structure.

oo. Regarding claim 12, it would have been obvious to one of ordinary skill in the art at the time the invention was made to give the vent plug anti-bacterial properties, as it would be art recognized as a location that bacteria could enter the IV system (even with a pour size of 5 micrometers as Bormann et al teaches) and then be introduced directly into the bloodstream of the patient, and using an anti-bacterial is notoriously well known to prevent this.

pp. Regarding claims 14 and 29, while Bormann substantially discloses the apparatus as claimed, it does not disclose a rigid impervious core in the absorbing material. However, Bormann discloses the invention may include additional layers or elements such as spacers and supports (Col.7 lines 37-40) and projections/ribs from the housing may interact directly with the porous material. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to project a projecting/rib into the center of the porous medium of Bormann to further support the porous material as taught by Bormann. An additional advantage would be the decrease in super absorbent materials would decrease the cost of the device.

qq. Regarding claim 27, see claim 11 above.

rr. Regarding claim 37, see claim 11 above.

ss. Regarding claim 38, see claim 15 above.

5. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann et al (6,336,916) in view of Meisch (4,465,479).

tt. Regarding claim 22, see claim 1 regarding the coupling assembly, drip chamber and patient conduit. While Bormann substantially discloses the apparatus as claimed, it does not disclose a splash guard for the vent plug. However, Meisch discloses an annular, conical splash guard for a drip chamber to protect the filter vents against gross or excessive splashing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide air vents for the vent plug as taught by Meisch to the filter of Bormann to protect against gross or excessive splashing.

Response to Arguments

Applicant's arguments, see Remarks/Arguments, filed 10/10/2008, with respect to the rejection(s) of many claim(s) under Ford in view of additional references have been fully considered and are persuasive. More specifically, it was agreed that Examiner was destroying the reference of Ford by placing the vertical filter horizontally. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bormann. The remainder of the arguments are moot as a new rejection is being introduced.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767